REMARKS

This Response is submitted in reply to the final Office Action mailed on November 24, 2010. The Office Action provided a three-month shortened statutory period in which to respond, ending on February 24, 2011. Accordingly, this Response is timely submitted. No fees are believed due with this Response. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Claims 1-10, 12-24, 26-33 and 36-47 are currently pending in this application. Claims 1-9, 33, 36, 37 and 41-44 were previously withdrawn from consideration. In the Office Action, Claims 10, 12-24, 26-28, 38-40 and 45-47 are rejected under 35 U.S.C. §102. Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Applicant has provided a current listing of claims for the convenience of the Patent Office. Additionally, Applicant respectfully requests reconsideration of the merits of the pending rejection for at least the reasons set forth below. Specifically, Applicant respectfully submits that the pending anticipation rejection is incorrect as a matter of fact and as a matter of law.

In the Office Action, Claims 10, 12-24, 26-28, 38-40 and 45-47 are rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/50054 to Mühlbauer ("*Mühlbauer*") as being evidenced by Kuttan et al. (*"Kuttan"*) and as evidence by J. Agric. Food Chem., 2005, 53(9): 3408-3014 to Wetli et al. ("*Wetli*"). Applicant respectfully submits that the cited references are deficient with respect to the present claims.

Independent Claims 10 and 24 recite, in part, nutritional and pharmaceutical compositions, respectively, comprising a γ-glutamyl-peptide selected from the group consisting of γ-glutamyl-alkyl-cysteine sulfoxide, γ-glutamy-alkenyl-cysteine sulfoxide, and combinations thereof, a carrier, and a fat source. Independent Claim 29 recites, in part, a method of obtaining a γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide by fractionation of an hydrophilic, ethanolic extract of Allium, the method comprising the steps of obtaining an hydrophilic,

ethanolic extract of Allium cepa, separating saccharides from fraction A, further separating saccharides from fraction A1, and further fractionation by semi-preparative reversed-phase HPLC (SP-RP-HPLC) using a solvent. Applicant has surprisingly found that the active constituent of allium responsible for the bone resorption inhibiting effect may be found in a hydrophilic, ethanolic extract of allium such as allium cepa. The active constituent having a potent inhibitory effect on bone resorption was identified as a γ-glutamyl-peptide, for example a γ-glutamyl-alkyl-cysteine sulfoxide or γ-glutamyl-alkenyl-cysteine sulfoxide, or a γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide. See, specification, page 7, lines 32-37. In contrast, *Mühlbauer* fails to disclose every element of the present claims.

For example, *Mühlbauer* fails to disclose or suggest nutritional and pharmaceutical compositions, respectively, comprising a γ-glutamyl-peptide selected from the group consisting of γ-glutamyl-alkyl-cysteine sulfoxide, γ-glutamy-alkenyl-cysteine sulfoxide, and combinations thereof, a carrier, and a fat source as required, in part, by independent Claims 10 and 24. Instead, *Mühlbauer* is entirely directed to plant extracts for the treatment of increase bone resorption. See, *Mühlbauer,* Abstract. The Patent Office asserts that *Mühlbauer* teaches a nutritional composition comprising all of the active components of the instant claims. See, Office Action, page 4, lines 14-16. Applicant respectfully disagrees, however, and respectfully submits that the Patent Office seems to be ignoring the tenants of patent office practice and legal precedent previously outlined by Applicant.

For example, the Manual of Patent Examining Procedure clearly states that "[a] genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named." *Ex parte A,* 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). Indeed, the disclosure of a large genus rarely anticipates a narrowly claimed species.

Further, in the Court of Customs and Patent Appeals case of *In re Petering,* a test for determining whether a disclosed genus is sufficiently small enough to anticipate a claimed species was established. 301 F.2d 676, (CCPA 1962). The application at issue in *Petering* contained claims to a particular species of compound. The Examiner cited a reference disclosing a chemical genus, which included the claimed species, having a limited number of substituent groups that represented either hydrogen or alkyl radicals, and an R group containing an OH

group. The court held that this formula alone could not anticipate the claimed species because there were too many compounds within this disclosed genus - the genus was too large. The reference, however, also disclosed preferred substituent groups, which included about twenty compounds defining a subgenus. The court found that one of ordinary skill in the art would have been informed enough by the reference to "at once envisage" each member of the subgenus, which included the claimed species. *Id.* Accordingly, the genus-species anticipation test states that a genus anticipates a species if one of ordinary skill in the art is able to "envisage" the claimed species within the disclosed genus. This test was later confirmed by the CCPA in *In re Schauman*, 572 F.2d 312, (CCPA 1978).

Recent Federal Circuit case law has confirmed that the *Petering* and *Schauman* analysis remains the test when considering whether or not a prior art document's disclosure of a genus anticipates a claimed species. See, *Sanofi-Synthelabo v. Apotex, Inc.,* 550 F.3D 1075, 1084 (Fed. Cir. 2008) and *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.,* 471 F.3d 1369, 1376 (Fed. Cir. 2006) (citing *Petering* and *Schauman* and emphasizing that the disclosure of a broad genus can be narrowed to a specific group of compounds if the reference also discloses preferred embodiments or compounds). As such, Applicant submits that, although *Mühlbauer* discloses the genus *allium* and mentions *allium cepa*, *Mühlbauer* fails to anticipate the present claims because the genus *allium cepa* is too large for the skilled artisan to envisage a γ-glutamyl-peptide extracted from *allium cepa*, let alone a specific γ-glutamyl-peptide selected from the group consisting of γ-glutamyl-alkyl-cysteine sulfoxide, γ-glutamy-alkenyl-cysteine sulfoxide, and combinations thereof as required, in part, by currently amended independent Claims 10 and 24.

Moreover, *Mühlbauer* also fails to disclose or suggest a method of obtaining a γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide by fractionation of an hydrophilic, ethanolic extract of *Allium*, the method comprising the steps of obtaining an hydrophilic, ethanolic extract of *Allium cepa*, separating saccharides from fraction A, further separating saccharides from fraction A1, and further fractionation by semi-preparative reversed-phase HPLC (SP-RP-HPLC) using a solvent as required, in part, by currently amended independent Claim 29. Indeed, *Mühlbauer* fails to disclose or suggest methods for obtaining a γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide by fractionation of an hydrophilic, ethanolic extract of *Allium*, let alone the specific steps necessary to accomplish the fractionation.

Kuttan and *Wetli* fail to disclose or suggest nutritional and pharmaceutical compositions, respectively, comprising a γ-glutamyl-peptide selected from the group consisting of γ-glutamyl-alkyl-cysteine sulfoxide, γ-glutamy-alkenyl-cysteine sulfoxide, and combinations thereof, a carrier, and a fat source as required, in part, by independent Claims 10 and 24. *Kuttan* and *Wetli* also fail to disclose or suggest method of obtaining a γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide by fractionation of an hydrophilic, ethanolic extract of *Allium*, the method comprising the steps of obtaining an hydrophilic, ethanolic extract of *Allium cepa*, separating saccharides from fraction A, further separating saccharides from fraction A1, and further fractionation by semi-preparative reversed-phase HPLC (SP-RP-HPLC) using a solvent as required, in part, by currently amended independent Claim 29.

In addition, Applicant also submits that the skilled artisan would not look to either *Kuttan* or *Wetli* as support for anticipation in view of *Mühlbauer*. For example, *Kuttan* is entirely directed to the isolation and characterization of γ-L-glutamyl-S-(trans-1-propenyl)-L-cysteine sulfoxide from sandal (*Santal album L.*). See, *Kuttan*, Abstract. At no place in the disclosure, however, does *Kuttan* disclose or suggest nutritional or pharmaceutical compositions comprising a γ-glutamyl-peptide selected from the group consisting of γ-glutamyl-alkyl-cysteine sulfoxide, γ-glutamy-alkenyl-cysteine sulfoxide, and combinations thereof, a carrier, and a fat source as required, in part, by currently amended independent Claims 10 and 24.

The Patent Office asserts that *Kuttan* demonstrates that the "γ-L-glutamyl-S-(trans-1-propenyl)-L-cysteine sulfoxide isolated from sandal (Santalum album L.) is the same as the protein isolated from onion (Allium cepa)." See, Office Action, page 5, lines 12-14. Applicant respectfully disagrees. Instead, Applicant notes that *Kuttan* expressly states that "[c]ircular dichorism measurements established that the sulfoxide group in the sandal and onion peptides are of opposite configurations." See, *Kuttan*, page 4394, column 2. The skilled artisan would immediately appreciate that stereoisomers of the same compound can have widely varying properties including, for example, efficacy in treating or preventing diseases or conditions characterized by bone resportion. Indeed, *Kuttan* also expressly states that "[d]ifferences in peak intensities [of the peptide derived from sandal and from onion] may be due to diastereoisomerism or variations in hydration. The onion peptide is extremely hygroscopic.

While the elemental analysis of the sandal peptide fits a monohydrate, it did not appear to be particularly hygroscopic." See, *Kuttan*, page 4396, bottom of column 1 to top of column 2.

Kuttan also states that "[t]he γ-L-glutamyl peptide . . . of S-(1-propenyl)-L-cystein sulfoxide . . . is the principal γ-glutamyl peptide of onion (Allium cepa) . . . being accompanied by lesser amounts of γ-glutamyl-S-(2-carboxypropyl)cystein . . . and S-methylcysteine . . . among others." See, *Kuttan*, page 4397, 1st paragraph of Discussion. As such, it is clear that *Kuttan* fails to remedy the deficiencies of *Mühlbauer* because the sandal peptide and the onion peptide are not, in fact, the same compound, as alleged by the Patent Office. Instead, the skilled artisan would immediately appreciate that the stereoisomers of the sandal and onion peptides most likely have widely varying properties that could include efficacy for the treatment or prevention of diseases or conditions that are characterized by increased bone resorption.

Wetli is cited by the Patent Office solely for the molecular mass of gamma-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide. See, Office Action, page 7, line 17-page 8, line 3. Accordingly, it is clear that *Wetli* also fails to remedy the deficiencies of *Mühlbauer*.

Further, anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, *e.g.*, *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found. In the instant case, the Patent Office has failed to identify the disclosure of each and every limitation of the claimed invention.

For at least these reasons, Applicant respectfully submits that *Mühlbauer* fails to disclose or suggest each and every element of the present claims.

Accordingly, Applicant respectfully requests that the anticipation rejections of Claims 10, 12-24, 26-28, 38-40 and 45-47 under 35 U.S.C. §102(b) be reconsidered and withdrawn.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly requests an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

By: /gml/
Gary M. Lobel
Attorney for Applicant
Reg. No. 51,155

Nestlé HealthCare Nutrition
12 Vreeland Road, 2nd Floor
Florham Park, NJ 07932
(973) 593-7553

Dated: 20 January 2011